

REMARKS

The Examiner has rejected claim 19 under 35 U.S.C. 112, second paragraph. Applicant has amended claim 19 to change the word "are" to "is" as required by the Examiner. Applicant submits that the remainder of the claim 19 language is acceptable, and that the Examiner's interpretation of it is correct. Thus, Applicant submits that this rejection should now be withdrawn.

Claims 1-10 and 12-26 are pending in the application. Claims 1, 2, 9, 10, 12, 13, 17, 19, and 20 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,648,158 to West (hereinafter, 'West'). Claims 1-20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. No. 4,800,879 to Golyakhovsky et al (hereinafter, 'Golyakhovsky') in view of U.S. Pat. No. 5,409,499 to Yi (hereinafter, 'Yi'). Claims 3, 4, and 16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over West. Claims 21-26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over West in view of U.S. Patent No. 5,833,700 to Fogelberg et al. (hereinafter, 'Fogelberg'). Applicant disagrees with these rejections, but has amended the claims to further define them over the cited art. Claims 6 and 10 have been cancelled by the present amendment, leaving claims 1-5, 7-9, and 12-26 as the claims pending in the application. Applicant respectfully traverses the rejections of the pending claims for the reasons set forth below.

Independent claim 1, as amended, is directed to **a surgical clip for use on a patient**, and includes, inter alia:

a) a first arm portion having a tip, a first opposite end, a first inwardly facing surface, and a first outwardly facing surface, said first arm portion defining a thickness between said first inwardly facing surface and said first outwardly facing surface, a first length between said tip and said first opposite end, and a first width which is transverse to said first length and said thickness of said first arm portion;

b) a second arm portion having a first end, a second opposite end, a second inwardly facing surface, and a second outwardly facing surface, said second arm portion defining a thickness between said second inwardly facing surface and said second outwardly facing surface, a second length between said first and second ends of said second arm portion, and a second width which is transverse to said second length and said thickness of said second arm portion;

c) a retainer **extending from said first end of said second arm portion, said retainer having a width which is identical to and parallel with said second width of said second arm portion, and a tissue piercing tip;** and

d) a bridge portion connecting said opposite ends of said first and second arm portions,

wherein **said first and second arm portions and said bridge portion comprise a single continuous piece of material,** and wherein

(i) said clip is configurable to an original first configuration in which said retainer extends beyond said tip of said first arm portion substantially parallel to said first and second arm portions,

(ii) said clip is configurable to an applied second configuration in which said tissue piercing tip of said retainer is disposed about or adjacent said tip of said first arm portion,

(iii) said retainer is adapted to plastically deform from its orientation in said original first configuration to its orientation in said applied second configuration, and

(iv) **said first and second arm portions and said bridge portion are adapted to maintain a generally U-shaped configuration in which said bridge portion extends through at least 90 degrees and said first and second arm portions are substantially parallel to each other in said original first and applied second configurations, and while said retainer is plastically deformed between said original first and applied second configurations.**

The cited art does not disclose or suggest these limitations.

Claims 1 is patentable over West.

Amended claim 1 requires a **surgical clip for use on a patient** which includes a retainer extending from the first end of the second arm portion and has a width which is transverse to the length and thickness of the second arm portion and **identical to and parallel** with the width of the second arm portion. None of the purported retainers of West 12, 14, 16 have widths which are identical to the arms from which they extend, as each is clearly narrower than the arm from which it extends. Providing retainers to West which have identical widths to the arms from which they extend would alter their function as the retainers of West overlap each other as they wrap around parallel wires.

Amended claim 1 also requires a plastically deformable retainer that has a **tissue piercing tip**. The Examiner asserts that West teaches a clip which is "capable of being used for surgical purposes" and includes retainers which have tips that are "capable of piercing tissue," but has not pointed to any disclosure within West in support of these statements. West contains no such disclosure or any suggestion thereof. Instead, West discloses a clip 8 which contains prongs 12, 14, 16 (the purported "retainers") designed to be wrapped around steel wires 30 of a lobster trap (FIG. 2; Col. 1, lines 47-49). The West clip is not a surgical clip, is not designed for use on a patient, and does not have a tissue piercing tip. In fact, the West clip is specifically designed to overcome the problem of U-clip induced cuts and abrasions on coated lobster trap wires caused by the prong members of the U-clips digging into and cutting the coating on the wires, which exposes the steel wire inside and causes electrolysis when salt water comes into contact with the wire through such cuts. These objectives are accomplished via the use of thin

flexible metal, and prongs which are beveled at the ends from the inside out so that when the prongs are bent around the wires, they slide by the plastic coating on the lobster trap wires without cutting into them. (Col. 1, lines 21-35, 58-62; Col. 2, lines 37-44). By disclosing a clip which is clearly designed to be non-intrusively bent around a steel wire of a lobster trap, West fails to disclose or suggest a **surgical clip for use on a patient** which includes a plastically deformable retainer that has a **tissue piercing tip** as required by claim 1.

As West does not disclose or suggest all of the limitations of claim 1, Applicant submits that claim 1 is patentable over West.

Claim 1 is patentable over Golyakhovsky in view of Yi.

The Examiner initially indicated that the amendment submitted with Applicant's prior response, which recited that the first and second arm portions and the bridge portion maintain a generally U-shaped configuration in which the first and second arm portions are substantially parallel to each other before, during, and after application of the clip to tissue of the patient, would likely distinguish the claimed invention over the Golyakhovsky reference. However, in the present office action, the Examiner now asserts that such language constitutes improper functional method steps, and moreover, that Golyakhovsky is capable of maintaining such a U-shaped configuration because when the arms are near each other, but not touching, "they will be substantially parallel, and a thin piece of tissue may be placed between the arms so that the clip may be applied to the tissue."

Applicant has amended the claims to more particularly claim specific configurations of the clip in which the plastically deformable retainer has different orientations relative to the arms, as well as to claim the structural capability of the arms and bridge of the clip to maintain a specific orientation during plastic deformation of the retainer between the claimed configurations. Prior to discussing these amended limitations, Applicant first notes that it disagrees with the Examiner's characterization of what constitutes purely functional language, and of the effect of functional language on the patentability of an apparatus claim.

MPEP 2173.05(g) states that "a functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used," and that such limitations are often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step. Further, elements which define structural attributes of interrelated component parts of a claimed assembly by reciting functional language are acceptable limitations. MPEP 2173.05(g), Citing *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976).

Claim 1 as currently amended requires that the first and second arm portions and the bridge portion are adapted to maintain a generally U-shaped configuration in which the first and second arm portions are substantially parallel to each other in the first

original and second applied configurations, and while the retainer is plastically deformed between the first original and second applied configurations.

Golyakhovsky is not adapted to maintain the first and second arm portions parallel to each other. Golyakhovsky discloses a loose hinge 3 which is specifically designed to allow rotation of the arms 1,2 relative to each other to close and open the device (Col. 3, lines 23-25). This is the opposite of maintaining the arms parallel to each other as required by claim 1. Golyakhovsky thus not only fails to disclose this limitation, but actually teaches away from it.

Golyakhovsky also fails to disclose a retainer which has a tissue piercing tip. The Golyakhovsky clip is designed to surround and occlude a blood vessel, not to rupture or pierce the blood vessel or tissue around it. The tip of the purported retainer 14a of Golyakhovsky is clearly blunt and meant for manual grasping, not for piercing tissue. Moreover, Golyakhovsky specifically states that "the invention provides an inexpensive, disposable, atraumatic vascular occluder which minimizes or eliminates rupture of the calcified wall of blood vessels, thus eliminating prior art surgery complications in the use of such devices." Col. 5, lines 35-39. Golyakhovsky thus teaches away from the use of a retainer having a tissue piercing tip as required by claim 1.

The Examiner admits that Golyakhovsky fails to disclose that the arms and bridge of the clip comprise a single continuous piece of material, but has cited Yi, which discloses a living hinge, to show this limitation. However, Yi does not resolve the

deficiencies of Golyakhovsky as it does not disclose or suggest a tissue piercing tip, two arms and a bridge connecting the arms and extending through at least 90 degrees, the arms and bridge maintaining a U-shaped configuration in original first and applied second configurations and during plastic deformation of the retainer. Moreover, Yi is not properly combinable with Golyakhovsky. Yi functions as a suture knot clip which has one closed position in which the second clamping surface 22 has been snapped into place under the beveled surfaces 6 facing the first clamping surface 20.

As the clip of Golyakhovsky functions to clamp an anatomy of indeterminate diameter such as a vein or an artery of the body in order to partially or fully block the blood vessel without rupturing it, the clip of Golyakhovsky is configurable to multiple closed positions via the latching mechanism 14a, 14b. The loose hinge 3, which does not maintain the position of the arms as discussed above, facilitates using multiple closed positions, which varies the pressure applied to a given anatomy and/or accommodates differently sized anatomies. Specifically, the latch 14a of Golyakhovsky is configurable to multiple positions of engagement with the toothed latch 14b to hold the device closed while facilitating and maintaining minimal compression, moderate compression, or maximum compression depending on the number of teeth engaged (Col. 4, lines 20-24). Thus, Golyakhovsky teaches away from use of a deformable retainer which interlocks in a single configuration as taught by Yi, and Yi teaches away from using flexible latching members that interlock in multiple configurations as taught by Golyakhovsky.

For all of these reasons, it is submitted that claim 1 is patentable over the cited art.

Claims 2-4, which depend from claim 1, are patentable for the same reasons that claim 1 is patentable, and for reciting additional limitations the combination of which are not shown or suggested in the cited art.

Claim 5 is patentable for the same reasons that claim 1 is patentable (with the exception that claim 5 does not recite a tissue piercing tip), and for reciting hook and catch portions provided at the tip end of the first arm portion and the retainer.

Claims 7-8, which depend from claim 5, are patentable for the same reasons that claim 5 is patentable, and for reciting additional limitations the combination of which are not shown or suggested in the cited art.

Claim 9 is patentable for similar reasons that claim 1 is patentable, and for reciting inwardly facing surfaces of first and second arm portions which face each other and outwardly facing surfaces of the first and second arm portions which are offset from each other **by no more than 2 mm**. Thus, claim 9 requires that the orthogonal distance across the first and second arms (e.g., between the outwardly facing surfaces of the first and second arms) be no more than 2 mm, a requirement not shown or suggested in the cited art.

Claim 12, which depends from claim 9, is patentable for the same reasons that claim 9 is patentable, and for requiring that the tip portion of the retainer be adapted to pierce tissue, which, as discussed above, is not shown or suggested in the cited art.

Claims 13 and 17, which require a first arm, second arm, and bridge which maintain a generally U-shaped configuration in which the first and second arm portions **are substantially parallel to each other during application of the clip to tissue of the patient**, are patentable for similar reasons set forth above with respect to these limitations in claim 1, and for requiring that the outwardly facing surfaces of the first and second arms be offset from each other **by no more than 2mm**.

Claims 14-16, which depend from claim 13, and claims 18-20, which depend from claim 17, are thus also patentable.

Claim 21, which requires a method which includes providing a surgical clip having patentable features similar to those discussed above with respect to claim 1 (e.g., a clip which maintains a generally U-shaped configuration in which the first and second arms are substantially parallel to each other before, during, and after application of the clip to tissue of the patient), and steps for applying the clip to tissue of the patient, is also patentable.

Claims 22-26, which depend from claim 21, are thus also patentable.

In light of all of the above, it is submitted that the claims are in order for allowance, and prompt allowance is earnestly requested. Should any issues remain outstanding, the Examiner is invited to call the undersigned attorney of record so that the case may proceed expeditiously to allowance.

Respectfully submitted,

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January 14, 2009